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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/528,577

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Ulrich Speck

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EXAMINER

BOUCHELLE, LAURA A

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

05/01/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/528,577	Applicant(s) SPECK ET AL.	
	Examiner LAURA A. BOUCHELLE	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Claim Rejections - 35 USC § 102

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1-9, 11, 14-20, 22-29, 31, 37-42, 44-46 are rejected under 35 U.S.C. 102(e) as being anticipated by Bates et al (US 2004/0073284).
3. Bates discloses a coated medical device comprising a lipophilic drug adhered to the surface of a medical device; the drug is released immediately upon contact with the tissue. The drug is carried on a balloon 26 having longitudinal folds 46, 48, 50 (Page 10, paragraph 0092). See Fig. 7. The drug may be paclitaxel (Page 2, paragraph 0014). The concentration on the surface of the balloon may be up to 5 $\mu\text{m}/\text{mm}^2$ (Page 8, paragraph 0068). The device may or may not include a stent.
4. Claims 5 are considered to be product by process claims. These claims are not limited to the manipulations of the recited steps, only the structure implied but the steps. The patentability of a product does not depend on its method of production. See MPEP 2113.
5. Bates discloses that the drug is in suspension that is sprayed on to the device in an ethanol solution (Page 8, paragraph 0068). The device of Bates may be used to treat vascular disease (paragraph 003) or a tumor (paragraph 0055).
6. Claims 47, 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Dror et al (US 5102402). Dror discloses a balloon for treating a body lumen having a drug coating on the smooth surface of the balloon. The device may or may not include a stent.

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7.

Claim Rejections - 35 USC § 103

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claims 10, 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bates in view of Desai et al (US 5916596).

10. Claims 10, 30 call for the drug to include amorphous structures with particle sizes ranging from 0.1 to 5 microns. Bates teaches that the drug is a quick dissolving lipophilic drug such as paclitaxel but fails to disclose the particle size. Desai teaches that it is known in the art to use paclitaxel particles having a diameter of less than one micron so that the drug can be delivered in vivo. See Abstract. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Bates to have the drug in particles of less than about one micron as taught by Desai so that the drug can be delivered in vivo regardless of its water solubility.

11. Claims 11-13, 31, 32, 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bates in view of Barry et al (US 6306166).

12. Claims 11-13, 31, 32, 36 differ from Bates in calling for the drug to be embedded in a readily water-soluble matrix, the matrix to be a low molecular weight hydrophilic substance. Barry teaches loading and release of water insoluble drugs such as paclitaxel in a low molecular weight matrix that allows the drug to be adhered to a medical device and still be absorbed into the tissue (Col. 15, lines 16-25). Therefore, it would have been obvious to one of ordinary skill

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in the art at the time of invention to modify the device of Bates to have the drug embedded in a low molecular weight matrix as taught by Barry so that the drug can have good adhesion to the medical device and be readily absorbed by the tissue.

13. Claims 21, 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bates in view of Ding et al (US 6364856).

14. Claims 21, 43 differ from Bates in calling for the device to be sterilized using ethylene oxide. Ding teaches a medical device with a coating for controlled drug release similar to that of Bates, but further including the step of sterilizing the device using ethylene oxide as is well known in the art (Col. 6, lines 57-59). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the method of Bates to include the step of sterilizing the device using ethylene oxide as taught by Ding because it is well known that devices to be inserted into a patient need to be sterilized and using ethylene oxide is an established technique for sterilization of medical devices.

15. Claims 33-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bates in view of Barry as applied to claim 31 above, and further in view of Klaveness et al (US 6177061).

16. Claims 33-35 differ from the teachings above in calling for the matrix to be a contrast agent, and the contrast agent is iopromide. Klaveness teaches the use of iopromide in a matrix material so that the matrix can be visualized when it is inside the body using x-ray (Col. 7, lines 14-35). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Bates in view of Barry so that the matrix is formed of the

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contrast agent iopromide as taught by Klaveness so that the substance can be visualized using x-ray.

Response to Arguments

17. Applicant's arguments filed 2/5/08 have been fully considered but they are not persuasive.

18. Applicant argues that Bates does not disclose or suggest the claimed concentration of the drug coating. The examiner disagrees as this is taught in the Bates disclosure as can be seen in paragraph 68 of Bates. Applicant argues that the device of Bates pertains to a stent and not a balloon. Bates clearly states that the device is a stent or a balloon having a bioactive material deposited thereon. The concentration disclosed by Bates uses the surface area of a stent as an example, but it is clear that the same concentration is contemplated for use with a balloon. The disclosure primarily describes the coating on a "base material" which can be a balloon or a stent, and then describes one or the other in specific examples of contemplated embodiments of the invention. Therefore, the Bates reference anticipates applicant's claims.

Conclusion

19. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA A. BOUCHELLE whose telephone number is (571)272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura A Bouchelle
Examiner
Art Unit 3763

/L. A. B./
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

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